JUN - 9 2011

510(k) Summary

A. Submitter's name, address, telephone number, contact person, and data summary was prepared

Submitter	Cardiac Science Corporation 3303 Monte Villa Parkway Bothell, WA 98021-8969
Contact Person	Kathleen Roberts Regulatory Affairs Manager Phone: (949) 797-3844 Fax: (949) 797-3801
Date Summary Prepared	March 24, 2011

B. Name of device, including trade name and classification name

Trade/Proprietary Name	Powerheart® AED G3 Semi-Automatic (Model 9300E) Powerheart® AED G3 Automatic (Model 9300A) Powerheart® AED G3 Pro (Model 9300P) Powerheart® AED G3 Plus (Models 9390A and 9390E)
Classification Name	Automated External Defibrillator
Classification Number	Class III, 21CFR 870.5310
Product Code	MKJ

C. Identification of the predicate device or legally marketed devices to which substantial equivalence is being claimed.

Company	Cardiac Science Corporation
Device	Powerheart® AED G3

Device Identification	Model Number	510(k) Number	Date Cleared
Powerheart® AED G3 Semi-Automatic	9300E	K031987	7/30/2003
Powerheart® AED G3 Automatic	9300A	K040438	7/1/2004
Powerheart® AED G3 Pro	9300P	K040637	8/6/2004
Powerheart® AED G3 Plus	9390A/E	K052161	10/21/2005

D. Description of the device

The Powerheart® AED G3 family of devices (Model numbers 9300A/E, model numbers 9390A/E, and model number 9300P) are portable, battery operated, automatic or semi-automatic, automated external defibrillators (AED). After applying the AED electrodes (pads) to the patient's bare chest, the AED automatically analyzes the patient's electrocardiogram (ECG) and guides the operator through the rescue using a combination of voice prompts, audible alerts, and visible indicators. For the Powerheart® AED G3 Automatic, the AED automatically delivers a shock if needed. For the Powerheart® AED G3 Semi-automatic, the AED uses one button and advises the operator to press the button and deliver a shock if needed.

The Powerheart® AED G3 family of devices includes a periodic automatic self-test feature. The focus of this submission is a software modification to enhance the detection capability of the device self-test feature.

E. Intended use of the device

The Powerheart® AED G3 family of devices is intended to be used by personnel who have been trained in its operation. The user should be qualified by training in basic life support or other physician-authorized emergency medical response.

The device is indicated for emergency treatment of victims exhibiting symptoms of sudden cardiac arrest who are unresponsive and not breathing. Post-resuscitation, if the victim is breathing, the AED should be left attached to allow for acquisition and detection of ECG rhythm. If a shockable ventricular tachyarrhythmia recurs, the device will change automatically and advise the operator to deliver therapy (G3) or automatically deliver the charge (G3 Automatic).

When the patient is a child or infant up to 8 years of age, or up to 55 lbs (25kg), the device should be used with the Model 9730 Pediatric Attenuated Defibrillation Electrodes. The therapy should not be delayed to determine the patient's exact age or weight.

Additional information exclusive to the Powerheart® AED G3 Pro, Model 9300P:

At the discretion of emergency care personnel, the G3Pro with ECG display enabled can also be used with Model 5111 ECG Patient Cable to display the rhythm of a responsive or breathing patient, regardless of age. The G3Pro and ECG Patient Cable system provides a non-diagnostic display for attended patient monitoring. While connected the G3Pro ECG Patient Cable, the G3Pro evaluates the patient's ECG and disables its shock capability.

F. Functional Tests

Software verification and validation testing has been successfully completed for all models of the modified Powerheart® AED G3 family of devices to demonstrate appropriate functional and performance characteristics.

G. Conclusion

Based on the results of the testing, it is concluded that the modifications to the Powerheart® AED do not raise any new questions regarding the safety or effectiveness as compared with the predicate device. The Cardiac Science Corporation Powerheart® AED G3 family of devices described in this submission is substantially equivalent to the previously cleared Powerheart® AED G3 products in terms of indications for use, features and functions.

There are no technological differences between the predicate devices and the modified devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JUN - 9 2011

Cardiac Science Corporation
c/o Ms. Kathleen Roberts
Regulatory Affairs Manager
3303 Monte Villa Parkway
Bothell, WA 98021

Re: K102496
Trade/Device Name: Powerheart AED G3 Models 9300A/E, 9390 A/E, and 9300P
Regulation Number: 21 CFR 870.5310
Regulation Name: Automated External Defibrillator
Regulatory Class: Class III (three)
Product Code: MKJ
Dated: May 10, 2011
Received: May 11, 2011

Dear Ms. Roberts:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you however, that device labeling must be truthful and not misleading.

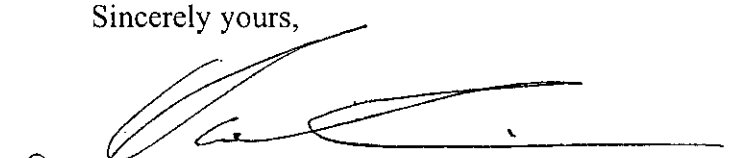
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K102496

Device Name: Powerheart® AED G3 Model 9300A/E
Powerheart® AED G3 Model 9390A/E
Powerheart® AED G3 Model 9300P

Indications for Use:

The Powerheart® AED G3 family of devices is intended to be used by personnel who have been trained in its operation. The user should be qualified by training in basic life support or other physician-authorized emergency medical response.

The device is indicated for emergency treatment of victims exhibiting symptoms of sudden cardiac arrest who are unresponsive and not breathing. Post-resuscitation, if the victim is breathing, the AED should be left attached to allow for acquisition and detection of ECG rhythm. If a shockable ventricular tachyarrhythmia recurs, the device will change automatically and advise the operator to deliver therapy (G3) or automatically deliver the charge (G3 Automatic).

When the patient is a child or infant up to 8 years of age, or up to 55 lbs (25kg), the device should be used with the Model 9730 Pediatric Attenuated Defibrillation Electrodes. The therapy should not be delayed to determine the patient's exact age or weight.

Additional information exclusive to the Powerheart® AED G3 Pro, Model 9300P:

At the discretion of emergency care personnel, the G3Pro with ECG display enabled can also be used with Model 5111 ECG Patient Cable to display the rhythm of a responsive or breathing patient, regardless of age. The G3Pro and ECG Patient Cable system provides a non-diagnostic display for attended patient monitoring. While connected the G3Pro ECG Patient Cable, the G3Pro evaluates the patient's ECG and disables its shock capability.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K102496